

Overview of a VFC Site Visit: Everything a Provider Needs to Know

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Overview of Visit

- Meet the Characters
- VFC Eligibility and Documentation
- Storage and Handling
- Conclusion



Meet the Characters Staff at Lots of Shots Pediatrics



- Dr. Benson –
Medical Director
and Owner
- Primary Contact –
Ashley, RN
- Back-up Contact –
Andrew, CNA




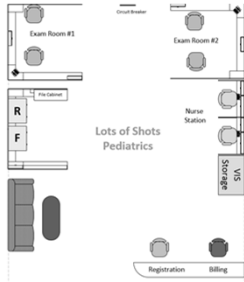
Meet the Characters

VFC Site Visit Reviewer

- Vicki Vaxscene –
Site Visit Reviewer




The Setting





VFC SITE VISIT




- Immunization Contact Changes
- VFC Eligibility Categories
- Billing
- Chart Audits
- Borrow/Return Activity
- Vaccine Management Plans
- Vaccine Information Statements (VISs)


Nurse Station


Vaccine Storage



Billing



ELIGIBILITY & DOCUMENTATION




Immunization Contact Changes

- All providers are required to report any change in primary or back-up contact or any change in Medical Director.
 - Reporting can be done through email, phone call or updated enrollment.
- Reporting updates to contacts is vital so that all pertinent staff are receiving important updates for VFC and state-supplied vaccine.





SAMPLE CONVERSATION #1



Annual Education

- At least two people from each provider site must complete the annual education each year.
 - You Call the Shots VFC Module
 - Keys to Storage and Handling Video
- All education completed after January 1, 2016 will count towards 2016 enrollment.
- The 2016 enrollment process should be sent out in mid-March.



VFC Eligibility

- Staff will be asked to list who is eligible to receive VFC vaccine.
- Coordinators will provide very little help so it isn't a bad idea to bone up on the different categories.
 - It is very important to have a working knowledge of the VFC eligibilities. This will reduce the number of borrows a practice has as well as keep you out of trouble for inappropriate use of vaccine!





SAMPLE CONVERSATION #2



VFC Eligibility Conversation

- What category(ies) did Ashley miss?



VFC Eligibility Sample Conversation

- What category(ies) did Ashley miss?
 - Underinsured
 - 18 years and younger
- Although adult programs are not covered in this question it is important for staff to be comfortable with this eligibility as well.
- State-supplied vaccine can be used for adults 19 years and older who are uninsured or underinsured.
 - Td, Tdap, MCV4, MMR and HPV only.
 - Other vaccines (including state-supplied influenza) should never be given to adults regardless of insurance status.



Billing Questions

- Billing questions must be answered by staff who work directly with billing.
 - Many times nurses or VFC contacts know what should be billed, but that doesn't necessarily mean that is what is actually being billed.
- Billing department personnel will be asked questions about administration fees and when, if ever, vaccine fees are charged to VFC or state-eligible patients.
 - Patients should never be billed for the cost of VFC or state-supplied vaccines.



Chart Audits

- At VFC site visits, reviewers will conduct chart audits on at least 10 patients who have been immunized at your clinic in the last six months.
 - For smaller clinics the doses may have been given in the last year or if there are not enough patients the audit will be less than 10 records.



Chart Audits, cont.

- VFC site visit reviewers are looking for the following with regards to eligibility:
 - Documented VFC eligibility on date of administration (Example: Medicaid, American Indian, Uninsured or Underinsured to those 18 and younger).
 - Proof of eligibility (Example: Insurance or Medicaid card) on date of administration.



Chart Audits, cont.

- Charts are also assessed for vaccine documentation following requirements set forth by Statute 42 US Code 300aa-25:
 - Address of clinic where vaccine was administered.
 - Name of vaccine administered.
 - Date vaccine was administered.
 - Date VIS was given.
 - Publication date of VIS.
 - Name of vaccine manufacturer.
 - Lot number.
 - Name and title of person who administered the vaccine.



Record Retention

- Providers are required to keep all records associated with the VFC program for a minimum of three years.
 - Part of the chart audit process is to assess if and how providers are keeping patient immunization records and VFC eligibility documentation for three years.
 - Electronic medical records (EMRs) make this easy as generally electronic data is not deleted from a patient record.
 - Other examples of documents that would need to be kept for three years are: temperature logs and packing slips.



Borrow and Return


- All doses that are borrowed must be replaced within four weeks of being borrowed.
 - Influenza vaccine can not always be paid back within four weeks.
 - Also influenza vaccine is approved for one directional borrowing only. Private influenza vaccine can be borrowed and used for VFC children if private inventory becomes available first. Providers can then pay themselves back once VFC stock is available. It is one directional because VFC stock cannot be used to supplement private influenza stock.
- Borrowing is allowed within the VFC program but must not happen routinely and cannot act as a replacement program for a provider's private inventory.
- All borrows must be documented in NDIIS and on a borrow and return form.




Borrow and Return, cont.

- Site visit reviewers will bring NDIIS reports showing:
 - 1) Current outstanding balances of vaccine owed to the state.
 - 2) Patient-based information on borrowing activity. This will be compared to the Borrow/Return forms the provider must have on hand.







SAMPLE CONVERSATION #3




Borrow and Return, cont.

- Vaccine borrowing is always going to happen to some extent as long as there are new staff members, insurance coverage issues, etc.
 - VFC site visits look for inappropriate borrowing, provider practices that rely heavily on borrowing and misuse of VFC or state-supplied vaccine.
- Always, always, always document borrowing in both the NDIIS (EMR if connected electronically to NDIIS) AND the borrow and return form.
 - Providers will need to enter private vaccine information into NDIIS for doses involved in a borrow or return.






SAMPLE CONVERSATION #4




Vaccine Management Plans

- Vaccine Management Plans are templates to help providers keep pertinent information in one spot.
 - Examples of areas found on the vaccine management template include:
 - Emergency relocation plan.
 - Phone numbers for vaccine manufacturers.
 - Primary and back-up coordinators.
 - Education log.
- Templates do not have to be sent in with annual enrollment.
- At a site visit the reviewer will make sure that all information is up-to-date, that the plan has been reviewed, and signed and dated in the last year.
- If a provider's vaccine management plan (contact or phone numbers) have not changed the provider simply needs to change the date the plan was last reviewed.




Vaccine Information Statements

- Vaccine information statements (VISs) are required by **federal law** to be given to every patient for every immunization.
 - This includes adults and kids, private and VFC vaccine and every dose given in a series.
- It is permissible to have laminated copies of VISs available for parents and patients to review.
 - If clinics are using laminated copies you must still ask the parent or patient if they want paper copies and must provide those to the patient or parent to take home.
 - Having laminated samples saves on paper wasted by patients throwing away VISs and reduces waste when VISs change.



VISs, cont.

- VISs contain very important information for vaccine recipients including:
 - Explains the disease you are vaccinating against.
 - Reviews vaccine recommendations.
 - Information on who should not receive this vaccine.
 - Lists what are “normal” reactions to this vaccine.



VAERS

- Vaccine Adverse Event Reporting System (VAERS)
- Reporting database for adverse events thought to have occurred following vaccination.
- Anyone can report to VAERS including the patient, parents, healthcare providers, state and local health departments and vaccine manufacturers.



VAERS, cont.

- Anyone can review VAERS data using the CDC wonder system.
<http://wonder.cdc.gov/vaers.html>
- When looking at VAERS data it is important to remember that anyone can report so that provides for a few limitations. This could make a certain adverse event look more prevalent than it truly is.
 - One event could be reported multiple times. (Example: event reported by patient, healthcare provider and state health department).



VAERS, cont.

- Data limitations:
 - Any event can be reported as a VAERS because it is up to the reporter to determine whether it was vaccine-related. (Example: patient receives an influenza vaccination and two weeks later is in a car accident and breaks their leg. This could be reported as an vaccine-related adverse event.)

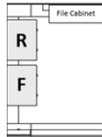


VAERS, cont.

- NDDoH gets a lot of calls from healthcare providers asking whether a specific event is related to a vaccine. In that situation is at the discretion of the healthcare provider as to whether they feel it is vaccine-related.
- The VIS lists some reactions that are considered normal following vaccination.
 - Generally redness and soreness would not be an adverse reaction as those symptoms are to be expected. However there can be special circumstances where that should still be considered.
- Use your best judgement to determine whether this is a normal reaction to vaccine or if it is something that should be reported.



- Storage Unit Checks
- Data Logger Evaluation
- Temperature Log Review
- Power Source Protection
- Vaccine Inventory Assessment



STORAGE AND HANDLING



SAMPLE CONVERSATION #5



Storage Unit Initial Assessment

- A few things that site visit reviewers will be looking at initially are:
 - Does the provider have a standalone or combination storage unit?
 - Is this a pharmaceutical or commercial/household unit?
 - Is there a thermometer in this unit?
 - Are there any obvious storage issues?
 - Is there sufficient room to store their current stock plus any additional doses for peak seasons without overcrowding?



Storage Unit Types

- Pharmaceutical vs. commercial/household
 - Pharmaceutical is the gold standard and is always recommended over household units.
 - That doesn't mean providers cannot use commercial/household units as long as they can maintain adequate temperatures.
 - If using a commercial combination unit (refrigerator and freezer in one – standard household unit) it is recommended to only use the refrigerator portion of this unit. Then providers should purchase a standalone freezer.



Standalone Units

- Standalone units don't have to be incredibly expensive and don't have to be full sized.
- Many providers call NDDoH worrying about having to find room for full-sized standalone units.
- There are many options for under-the-counter sized standalone units.
- Purchasing guides for data loggers, refrigerators and freezers are available on the NDDoH website.



Data Loggers

- Providers are required to use data loggers in all storage units that store VFC or state-supplied vaccines.
- Data loggers are assessed at site visits for several items.
 - If you are still using the FridgeTag® data loggers that were provided by NDDoH or have purchased new FridgeTags® they will meet all of these criteria.
 - There are now many brands of data loggers that meet all of CDC criteria so when replacing them you are not required to purchase the same ones you were given.
 - Providers can find alternative brands and a listing of the required data logger elements here:
<http://www.ndhealth.gov/Immunize/Documents/Providers/Forms/Dataloggerpurchasingguide2016.pdf>



Subtle Hint

- **MANY DATA LOGGERS EXPIRE IN APRIL SO PLEASE START ORDERING NEW DATA LOGGERS!!**
- Providers will receive corrective actions if either their data logger or back-up data loggers have expired.
- Other data loggers will expire in late summer or early fall.



SAMPLE CONVERSATION #6



Thermometer Placement

- Thermometer probes (liquid bottle inside of storage unit) should always be stored as centrally located as possible and always stored with the vaccine.
 - If thermometer probes drop to the back of the refrigerator, get pushed to the walls or lay under a cooling vent it can drastically effect your temperatures.
 - If the probe is not stored directly with vaccine you may not be assessing what temperature your vaccine is being stored at.



Temperature Log

- Providers are required to monitor temperatures on a paper temperature log even though a continuous recording device is also being used.
- This is to increase accountability and to ensure that staff are actually looking at the data logger to make sure temperatures are within range.
- On every day the clinic is open providers should have twice daily temperature checks where time, date and staff initials are recorded.



SAMPLE CONVERSATION #7



Temperature Excursions

- Notify primary vaccine coordinator
- Reposition thermometer probe in central location of storage unit
- Recheck temps in ½ to 1 hour
- Add additional water bottles/ice packs to unit
- Check door seals
- Relocate vaccine, if necessary



Temp Excursions, cont.

- Temperatures still out of range: *what do I do?*
 - Vaccine manufacturers should be contacted first to determine vaccine viability
 - Do NOT assume that vaccine is not viable
 - Do NOT discard any vaccine until the NDDoH has been notified
 - Label the vaccine as “DO NOT USE”
- All actions must be recorded and submitted monthly with temperature logs
- **Even one out-of-range temperature, especially on the cold side, may result in the need for revaccination!**



SAMPLE CONVERSATION #8



Vaccine Unit Inspection

- In case you missed all the items the site visit reviewer was looking for here's a list:
 - Vaccines centrally located and enough space for air circulation.
 - Original packaging.
 - Private stock and VFC is clearly marked.
 - Water bottles or gel packs.
 - Inappropriate food storage.
 - Expired vaccines.
 - Carries all ACIP recommended vaccines.



Power Supply Protection

- Both circuit breakers and plug-ins used for vaccine storage units will be assessed to make sure they are clearly marked so that the power supply to the storage unit is not interrupted.
- Facilities who are connected to a generator should have a comprehensive written policy detailing measures taken to prevent loss of power.



Power Supply Protection, cont.

- It may seem obvious to a healthcare provider not to unplug a storage unit that houses thousands of dollars of vaccine.
- However annually there are many situations where storage units are unplugged by unsuspecting employees due to:
 - Scheduled or unscheduled moves.
 - Recarpeting or new flooring.
 - Cleaning or waxing.
 - Remodeling.
 - Storage Unit replacement.



Power Supply Protection, Cont.

- Even when providers have signs in place, mistakes can be made.
- A good rule of thumb is to place a piece of tape over the actual breaker that controls the power source to the units. That way if someone goes to flip the breaker they cannot because it is covered by the piece of tape. Hopefully this will cause them to ask why it is protected or not flip the breaker, when they otherwise would have.



Review Follow Up Items
Establish Timeline for Follow Up

CONCLUSION



SAMPLE CONVERSATION #9



Lots of Shots Follow Up Plan

- Immediately:
 - Provide a copy of the packing slip showing purchase of PCV13.
 - Email site visit reviewer when you have placed water bottles or gel packs in storage units.



Lots of Shots Follow Up Plan, cont.

- One month later:
 - Review VFC eligibility category (previously missed two eligibilities).
 - Check on balances of vaccine owed to state. The balance should be zero after one month or significant progress made towards zero.
 - Provider should send in a complete temperature log showing twice daily temperature checks with time, date and staff initials.



Lots of Shots Follow Up Plan, cont.

- Six months later:
 - Site visit reviewer will pull NDIIS report showing any borrow or return occurrences since site visit. Provider will then be requested to send in borrow and return forms documenting any borrowing activity.



Type your question to the right in the
chat window

After the presentation, questions may be sent to:

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**Immunization Program : 701.328.3386 or
toll-free 800.472.2180**



Post-Test Information

- Post-test
 - Nurses interested in continuing education credit, visit:
<http://www.ndhealth.gov/disease/post/default.aspx?PostID=121>
 - Successfully complete the five-question post-test to receive your certificate.
- Credit for this session is available until Tuesday, April 12, 2016.
- This presentation will be posted to our website:
www.ndhealth.gov/immunize